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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TRAN, MY CHAUT

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 07/10/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/878,108	Applicant(s)	CHILDERS, WINTHROP D.
Examiner	My-Chau T. Tran	Art Unit	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 April 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 11-26 and 31-35 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 and 27-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 17 April 2003 is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 4/17/03 in Paper No. 9 is acknowledged and entered.

Claims 1, 2, 4, 5, 6, and 10 are amended by the amendment. Claims 27-35 are added by the amendment.

2. Claims 1-35 are pending.

Election/Restrictions

3. Newly submitted claims 31-35 are directed to an invention that is related to Group V (Claims 25-26) of the originally presented claims (Claims 1-26). The invention of Group V was not the invention elected for prosecution on the merit.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. This application contains claims 11-26 and 31-35 are drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

5. The corrected or substitute drawings were received on 4/17/03. These drawings are acceptable.

Withdrawn Rejections

6. The previous rejection 35 USC 112, first paragraph, for claim 4 has been withdrawn in view of applicant's amendment of claim 4, and amendment of paragraph [0065] of the specification.

7. The previous rejections 35 USC 112, second paragraph, for claims 1-10 have been withdrawn in view of applicant's amendments of claims 1, 2, 4, 5, 6, and 10.

8. Claims 1-10 and 27-30 are treated on the merit in this Office Action.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

10. Claims 1-10 and 27-30 (newly added claims) are rejected under 35 U.S.C. 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214). (*Note: the newly added claims 27-30 would now also be included in this rejection.*)

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9). The method comprise of dispensing the reagents (pharmaceutical active agent) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9). The method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The automated method can comprise of multiple dispensers for dispensing different reagents in a complex screening process (col. 33, lines 32-48) (referring to claim 10). Therefore, Stylli et al. anticipate the presently claimed invention.

Response to Arguments

11. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214) for claims 1-10 were considered but they are not persuasive for the following reasons.

Applicant alleges that “[S]tylli reference fails to teach or suggest the use of an apparatus having a liquid ejection device that acts in cooperation with an electronically activated printhead. Stylli reference fails to teach or suggest the step of generating information indicative of an effect of the at least one potentially active agent and analyzing the generated information to generate a

correlation factor. Stylli does not teach the use of a removably associatable cartridge. Stylli reference fails to teach or suggest the step of interactively activating at least one second liquid ejection device.” Therefore, Stylli does not anticipate the invention.

Applicant’s arguments are not convincing since Stylli et al. do teach ‘an apparatus having a liquid ejection device that acts in cooperation with an electronically activated printhead.’ Stylli discloses that ‘the electrically sensitive volume displacement unit is in vibrational communication with a dispensing nozzle so that vibration ejects a predetermined volume from the nozzle’ (col. 16, lines 39-42). Additionally, Stylli et al. disclose that ‘the work flow and assay design area of the data store typically defines the work process to be performed, and parameters necessary to control the automation of the system’ (col. 30, lines 59-62) (refers to ‘generating information indicative of an effect of the at least one potentially active agent and analyzing the generated information to generate a correlation factor’) and that ‘*the system can include a storage and retrieval module that can house a plurality of chemicals in solution in addressable chemical wells*’ (col. 7, lines 55-57; fig. 5, ref. #306) (refers to ‘a removably associatable cartridge’). Further, Stylli et al. disclose that ‘*the computer not only monitors the status of key sensors (e.g., reagent bottle pressure, liquid level, plate position, and positioning limit switches) but also provides the interface for generating specific liquid dispensation patterns and volumes to the high density plate*’ (col. 60, lines 3-8) (refers to ‘the step of interactively activating at least one second liquid ejection device’). Therefore, Stylli et al. anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

12. Claims 1-10 and 27-30 (newly added claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US Patent 6,083,763) in view of Stylli et al. (US Patent 5,985,214). (***Note: the newly added claims 27-30 would now also be included in this rejection.***)

Balch discloses a method of drug screening in a 96-well sample plate (fig. 17; col. 9, lines 11-13). The drug reacts with biosite (cellular material) in the 96-well sample plate. The biosites comprise of biological molecules that are deposited on the top surface of the substrate (col. 9, lines 24-26). The 96-well sample plate is scanned by a scanning mechanism to produce an image (capturing data).

The method of Balch does not expressly disclose that the drug is dispensed onto the cellular material.

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9). The method comprise of dispensing the reagents (pharmaceutical active agent) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9). The

method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The method of Stylli et al. would provide the advantage of reducing the volume of sample processes and consumable cost (col. 9, lines 7-15).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method of dispensing drug onto the cellular material as taught by Stylli et al. in the method of Balch. One of ordinary skill in the art would have been motivated to include the method of dispensing drug onto the cellular material in the method of Balch for the advantage of providing a reduction in the volume of sample processes and consumable cost (Stylli: col. 9, lines 7-15) since both Balch and Stylli et al. disclose an assay format in a 96-well plate (Balch: fig. 17; col. 9, lines 11-13; Stylli: col. 15, lines 42-44).

Response to Arguments

13. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Balch (US Patent 6,083,763) in view of Stylli et al. (US Patent 5,985,214) for claims 1-10 were considered but they are not persuasive for the following reasons.

Applicant contends that Bach and Stylli et al. is not obvious over the presently claimed invention because '[B]ach reference fails to teach or suggest a test method that can be employed on samples containing intact cells and/or recognizable material from intact cells having measurable masses greater than molecular levels' and '[S]tylli reference lacks any teaching which would suggest dispensing of material from at least one liquid ejection device acting in cooperation with an electronically activated printhead'.

Applicant's arguments are not convincing since Bach and Stylli et al. is obvious over the presently claimed invention because the term "substance containing cellular material" as define

in the specification includes ‘[r]ecognizable material from intact cells, for example mitochondria, golgi bodies, nuclei, nucleoli and the like’, which encompasses the Bach definition of “biosite” material that includes “biological molecules”. Stylli et al. do teach ‘dispensing of material from at least one liquid ejection device acting in cooperation with an electronically activated printhead’ as discussed above. Therefore, Bach and Stylli et al. is obvious over the presently claimed invention.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant Claim 29 briefly recites the method step of positioning at the volume of a substance containing cellular material on a suitable testing apparatus.

The recitation of ‘a method step of positioning at the volume of a substance containing cellular material on a suitable testing apparatus’ claimed in claim, have no clear support in the specification and the claims as originally filed. The support as indicated by applicant is Claim 3, which disclosed *‘wherein the defined volume of the substance containing cellular material is*

maintained in contact with a suitable testing substrate, the suitable testing substrate having a contact surface which is reactively inert to interaction with the cellular material under study.' is not support for '*the method step of positioning at the volume of a substance containing cellular material on a suitable testing apparatus*'. Because the limitation of Claim 3 recites the "interaction" of the cellular material with the testing substrate, does not support the limitation of the Claim 29, which recites a method step of how the "volume of the cellular material" is place (i.e. positioning) on the "testing substrate". Therefore, the scope of the invention as originally disclosed in the Claim 3 would not encompass the scope of the limitation of the method step of positioning at the volume of a substance containing cellular material on a suitable testing apparatus.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 27-28 recite the limitation "removable cartridge" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
July 9, 2003



ANDREW WANG
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